K083014

Appendix A

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Classification and Device Name

OCT 17 2008

Classification Name

Coil, magnetic resonance, specialty; 21 CFR 892.1000 [90-MOS]

Model Number

MJAH-137A

Trade/Propriety Name

Atlas SPEEDER Head/Cervical

2. Establishment Registration

2020563

3. U.S. Agent Name and Address

Agent Name

Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, CA 92780

Contact Person

Paul Biggins, Director Regulatory Affairs
T: (714) 730-5000
F: (714) 730-1310
pbiggins@tams.com

4. Manufacturing Site

Toshiba Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi-Ken
Japan 324

5. Date of Submission

September 30, 2008

6. Device Intended Use

The MJAH-137A Atlas SPEEDER Head/Cervical Coil is intended for the use of diagnostic imaging of the human body, fluid visualization, 2D and 3D imaging, MR angiography and MR fluoroscopy.

This coil is intended to be used on the Atlas Vantage, model numbers MRT-1503/S3, /S4 and Atlas Titan, model number MRT-1504.

7. Device Description

The Atlas SPEEDER Head/cervical is a phased Array Coil that can receive NMR signal from head, cervical region and upper chest.

The coil is configured in three sections; a head base, a removable anterior coil, and NV chest coil. There are two types of anterior coil; 1) Head anterior coil for head imaging, and 2) Neck anterior coil for cervical imaging. The Neck anterior coil includes an adjustable NV coil which is combined with Head anterior coil.

During transmission by the QD body coil this coil is deactivated by means of PIN diodes located on the internal circuit board. Upon deactivation of the transmit cycle the coil switches on to the receive mode.

8. Safety Parameter

Maximum static field strength

1.5 T

Maximum dB/dt

1st operation mode specified in IEC60601-2-33 (2005)

Maximum SAR

1st operation mode specified in IEC60601-2-33 (2005)

Peak and A-weighted Acoustic Noise Level

Not applicable

Biocompatibility

All materials used in contact with the patient will have a history of use or test data that demonstrates its biocompatibility, i.e., non-toxic, non-irritating.

9. Imaging Performance Parameter

Sample phantom images and clinical images are presented in Appendix F & G.

10. Equivalency Information

Toshiba Medical Systems Corporation believes that this Atlas SPEEDER Head/Cervical is substantially equivalent to the current Atlas SPEEDER Head [K063361] and SPEEDER 1.5T Wrist coil [K072935].

11. Software

There is no additional software required for this coil.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K083014
Trade/Device Name: Model MJAH-137A Atlas SPEEDER Head/Cervical COil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 8, 2008
Received: October 9, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083014

Device Name: **Model MJAH-137A Atlas SPEEDER Head/Cervical Coil**

Indications for Use:

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This coil is intended to be used on the Atlas Vantage, model numbers MRT-1503/S3,S5 and the Atlas Titan, model number MRT-1504.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083014